Exhibit 34-1

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben
in Support of Defendants' Joint Motion for Partial Summary Judgment

A Survey of Acquisition Costs
of Pharmaceuticals in the
State of California

Prepared for the

California Department of Health Services

June 2002

Myers and Stauffer LC

Certified Public Accountants

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EXHIBITS

Executive Summary

Introduction

Under contract to the California Department of Health Services, Myers and Stauffer LC performed a study of the adequacy of Medi-Cal pharmacy reimbursement rates. A key piece of pharmacy reimbursement is the component for pharmaceutical ingredient cost. A discussion of the adequacy of Medi-Cal reimbursement rates would not be complete without an analysis of Medi-Cal's allowance for ingredient cost compared to the actual cost incurred by pharmacies to acquire drug products.

This report includes a narrative of the methodologies and findings relevant to the survey of pharmaceutical acquisition costs. As there is significant detail required to present the methodology and findings of the study of pharmacy acquisition cost, the acquisition cost aspect of the comprehensive study of Medi-Cal pharmacy reimbursement is presented independently. A separate report issued by Myers and Stauffer LC includes discussion of the survey of pharmacy dispensing cost and incorporates the findings from both the surveys of pharmacy dispensing and acquisition cost into a general discussion of the adequacy of Medi-Cal pharmacy reimbursement rates.

Drug acquisition cost comparisons were compiled and analyzed for the top 2,000 drug products (as measured by Medi-Cal expenditures in calendar year 2000) of the Medi-Cal pharmacy program. This sample of drug products constitutes over 90% of the payments made by the Medi-Cal pharmacy program. A random sample of 2,010 pharmacies participating in the Medi-Cal program were asked to participate in the study by submitting pharmaceutical purchase invoices for one month from calendar year 2000. Invoices were received from a sufficient representative sample of Medi-Cal participating pharmacies and analyzed. Pharmacies that responded included an appropriate mix based upon factors relating to retail versus institutional settings, independent versus chain affiliation, urban versus rural location, and certain pharmacy specialties. The actual acquisition cost data shown on invoices obtained from California pharmacy providers was compared to the standardized Average Wholesale Price (AWP) and Direct Price (DP). Actual acquisition costs were also compared to the Federal Upper Limit (FUL) for those multi-source drugs with federal maximum

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allowable costs, and to the California Maximum Allowable Ingredient Cost (MAIC) for those multi-source drugs with state maximum allowable costs.

Summary of Findings

The significant findings of the study are as follows:

- For the 272 pharmacies that provided invoices from external wholesalers, typical acquisition costs for single source drugs ranged from 82% to 84% of the AWP. The average acquisition cost was 82.8%, with a standard deviation of 1.2%.

- Some of the pharmacies in the sample were institutional providers that dispensed prescriptions to patients in long-term care or other institutional settings. Acquisition costs at these pharmacies for single source drug products averaged 82.1% of the AWP, as compared to 82.9% for pharmacies that dispensed prescriptions in traditional retail settings.

- Of the sampled 1,000 single source drugs, 796 drug products were matched to one or more purchases. Of these 796 products, typical acquisition costs for single source drugs ranged from 79% to 84% of the AWP with an average acquisition cost of 81.7% of the AWP. The average actual drug acquisition cost is considerably less than the Department's current ingredient cost allowance of AWP minus 5.0% (95% of the AWP).

- For the pharmacies in the sample with external invoices, the average acquisition cost for single source drug products paid with a Direct Price (DP) was 94.5% of the DP, with a standard deviation of 2.3%.

- The acquisition costs for multi-source drugs exhibited much greater variation, but averaged 56.6% of the AWP (mean weighted by Medi-Cal volume) for drugs without FUL prices. For multi-source drugs with FUL prices, the weighted average acquisition cost was 12.7% of the AWP and 38.7% of the FUL.

Conclusions

There are several factors that should be considered in determining an appropriate Medi-Cal pharmacy reimbursement formula besides dispensing and drug acquisition costs incurred by pharmacies. These factors include market dynamics (i.e., the rates accepted from commercial third-party payers) balanced with the need to maintain sufficient access to services for Medi-Cal recipients throughout the state.

Findings from this study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs

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actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10. These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement. In our separate report, Myers and Stauffer has incorporated the findings from this acquisition cost study into a more comprehensive analysis of Medi-Cal pharmacy reimbursement.

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Chapter 2

SURVEY OF ACQUISITION COSTS

The largest component of pharmacy reimbursement is payment to pharmacies for prescription drug ingredient costs. Most states base ingredient reimbursement on the Average Wholesale Price (AWP), which is available from published sources. Recent studies, including those performed by Myers and Stauffer LC in other states, have shown that pharmacies are able to purchase drugs at prices that are significantly below AWP. To determine the level of discount from AWP currently available to California pharmacies for the drugs most commonly dispensed to Medi-Cal recipients, Myers and Stauffer LC performed a study of drug acquisition costs.

Methodology

Development of Methodology

The study of acquisition cost is based upon a simple comparison of prices paid by pharmacies with the AWP in effect at the time of the drug purchase. Drug purchase prices for each pharmacy were obtained from the pharmacy's own invoices. Myers and Stauffer LC has used this method to study pharmaceutical acquisition costs in several previous surveys. Such a technique has also commonly been used by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services.[1] Results of previous studies performed by Myers and Stauffer LC and the OIG are included in Appendix B of this report.

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[1] The OIG has also used price lists obtained directly from wholesalers. The process to obtain such price lists could face legal obstacles and does not yield as compelling evidence of the actual price paid by a pharmacy as could be obtained from an invoice.

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Drug Product Selection

Myers and Stauffer obtained a summary of the utilization of the pharmacy program by drug product from the Department of Health Services. Using this summary, a list of the top 1,000 single source and top 1,000 multi-source drug products ranked by total reimbursement for the calendar year ending December 31, 2000, was created. The drug summary file contained the following data elements summarizing utilization for each drug product:

- Number of prescriptions
- Number of units
- Dollar amount reimbursed

Myers and Stauffer also obtained the following price information for each drug product for the sample months of May and November 2000:

- Average Wholesale Price
- Direct Price (if applicable)
- Federal Upper Limit price (if applicable)
- California Maximum Allowable Ingredient Cost (if applicable)

As summarized in the table below, the 2,000 drug products analyzed represent approximately 93% of California Medi-Cal drug reimbursement.

Table 2.1 Utilization Overview for Drugs in Sample

Drug Classification	Total Program Reimbursement[1]	Program Reimbursement for Sampled Drug Products[1]	Percent of Top Drugs in Total Program Reimbursement
Single Source Products	$1,710	$1,694	99%
Multi-Source Products	$655	$508	77%
Total	$2,365	$2,202	93%

[1] In millions

Pharmacy Sample Selection

Myers and Stauffer received a pharmacy provider file from the Department of Health Services that included the following information:

- Provider Numbers
- Provider Names

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- Provider Address and Phone Number Information
- Prescription Claim Count for Calendar Year 2000
- Prescription Claim Dollar Amount for Calendar Year 2000

There were a total of 5,902 pharmacies included in the provider file.

Myers and Stauffer also received a sample of pharmacy claims for the months of May and November 2000.

Based on an analysis of predicted statistical variation, expected participation rates and other considerations, Myers and Stauffer developed a survey plan that involved soliciting participation in the acquisition cost survey from approximately 2,000 pharmacies. The selection criteria for the sample was primarily random, however certain stratification protocols were implemented to promote adequate representation of various pharmacy specialties. Myers and Stauffer determined that certain pharmacy traits were broadly distributed, and were therefore appropriately captured in adequate numbers in a random sample. There were also some attributes for which better representation was obtained via a stratification process.

After importing the pharmacy provider data into internal database formats, Myers and Stauffer performed a process of making preliminary identifications of pharmacy specialties. Various "flags" were created for the purpose of performing appropriate sample stratification. Pharmacy attributes that were flagged are as follows:

- **Chain versus Independent Affiliation**
  Myers and Stauffer made a preliminary determination of chain versus independent based on a preliminary visual inspection of the provider file. As applicable, Myers and Stauffer staff also utilized their experience with and exposure to various national chain organizations. For the purposes of this project, a chain was considered an entity with five or more stores nationally.

- **Urban versus Rural Location**
  Myers and Stauffer used zip code data to crosswalk the pharmacy location to individual California counties. A county was deemed to be "urban" based on its location in a "Metropolitan Statistical Area" (MSA) as used by the Bureau of the Census. Other counties were considered "rural." Pharmacies not physically located in the state of California were not classified as to urban or rural status.

- **Long-Term Care Pharmacy Provider Status**
  The pharmacy provider data included "place of service" codes. One code is used to identify claims dispensing in a nursing facility. Myers and Stauffer used these codes to determine the ratio of prescriptions dispensed to Medi-Cal recipients that resided in long-term care facilities. Pharmacies that

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dispensed 50% or more prescriptions in a long-term care setting were identified. A few additional providers were also classified based on name recognition of the provider.

- **Provision of Intravenous Prescription Services**
  Myers and Stauffer used the sample of pharmacy claims data to identify certain pharmacies that dispensed a significant portion of intravenous medications.

- **Provision of Other Compounding Services**
  Myers and Stauffer received lists of pharmacies that provide compounding services from the Department of Health Services, a local pharmacist recommended by the Department, and from the web site of the International Academy of Compounding Pharmacists (IACP) [2].

Low Volume Exclusion from Pharmacy Sample
Prior to selecting any pharmacies into the random sample, Myers and Stauffer excluded all pharmacies that dispensed fewer than 250 prescriptions during calendar year 2000. Approximately 1,200 pharmacies were excluded based on this criteria. It has been our experience that these pharmacies with low volume of Medi-Cal prescriptions often are out-of-state, newly opened, or recently closed pharmacies. As such, these pharmacies do not represent the norm of Medi-Cal participating providers. Additionally, our experience has shown that due to their low Medi-Cal volume, many of these pharmacies would be reluctant to spend the time and effort required to participate in the survey. These pharmacies also have little impact on the overall cost structure of pharmacies in the Medi-Cal pharmacy program (and conversely are often only minimally impacted by the Medi-Cal program). Collectively, all of these low Medicaid volume pharmacies dispensed less than one-quarter of one percent of Medi-Cal prescriptions in calendar year 2000.

Stratification Protocols Based on Pharmacy Specialty
Based on our preliminary analysis, there were certain specialties that were not broadly distributed among the pharmacy population (exclusive of the low Medi-Cal volume pharmacies previously described). In particular we noted that there were 201 pharmacies that met the criteria for the long-term care pharmacy provider designation. Also, there were only 100 pharmacies identified that dispensed intravenous prescriptions as a significant portion of their volume. There were 63 pharmacies designated to be the compounding specialty. Myers and Stauffer believed that in order to ensure adequate representation of specialties represented by these flags, 100% of the pharmacies so identified should be included in the sample.

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[2] "http://www.iacprx.org/"

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Stratification Protocols Based on Pharmacy Location

It was noted that there were only 200 pharmacies located in counties designated as "rural." Due to this relatively small number of rural providers, Myers and Stauffer included 100% of these pharmacies in the sample. Additionally, Myers and Stauffer developed a computer algorithm to ensure that each California county was represented by at least five pharmacies in each county (or all eligible pharmacies in the case of a county with less than five pharmacies).

Random Selection

After including the stratification groups identified previously, a computer algorithm randomly selected from the remaining pharmacies for inclusion in the survey sample.

Survey Procedures

The final sample of Medi-Cal pharmacy providers selected by the above process included 2,010 pharmacies. All pharmacies were sent a letter from the California Department of Health Services informing them that Myers and Stauffer would be performing a survey of pharmacy acquisition cost (see Exhibit 1). Pharmacies also received a request that they copy drug purchase invoices covering a one-month period. One-half of the pharmacies were requested to send invoices from May 2000, and the other half from November 2000 (see Exhibit 2). Pharmacies were requested to submit invoices for drug purchases from both wholesalers and manufacturers. This request to submit invoices was issued in conjunction with an additional request for the pharmacy to participate in the dispensing cost survey.

A small number of pharmacies indicated an inability to participate in the acquisition cost survey due to being recently opened or experiencing a change of ownership in the last six months (which precluded financial records from being available for the requested period). Additionally, there were a limited number of invoices received that did not meet the criteria for use in the survey. The primary problems with these invoices included invoices from the incorrect year or month, purchase summaries that encompassed an extended time period, or invoices that lacked a standardized identifier (i.e. NDC or wholesaler item code).

Ultimately, usable invoices were received from 491 of the selected pharmacies after follow-up efforts to encourage participation. Characteristics of the total sample of 491 pharmacies compared to the study's eligible population are presented in Table 2.2.

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Table 2.2 Sample Pharmacy Characteristics

Pharmacy Trait	EAC Study Eligible Population[1]	Pharmacies Included in EAC Analysis
Number of Pharmacies	4,673	491
Average Annual Medi-Cal Volume	10,243	12,090
Medi-Cal Volume Standard Deviation	17,977	16,409
Percent Chain	51.0%	50.1%
Percent Urban	95.5%	89.0%
Percent Institutional	4.3%	3.7%
Percent Intravenous	2.1%	2.4%
Percent Compounding	1.4%	2.6%

[1] Excludes pharmacies with Medi-Cal volume less than 250 prescriptions annually.

For the traits listed in Table 2.2, the sample of 491 pharmacies was tested to determine if it was representative of the population of Medi-Cal provider pharmacies. Since the response rate of the sample pharmacies was less than 100 percent, the possibility of bias in the responding sample should be considered. To measure the likelihood of this possible bias, chi square (χ^2) tests were performed.

Among other attributes, a chi square test was used to determine whether the final sample was independent with respect to traits that were assumed to be broadly distributed. It was determined that the sample was representative with regard to chain and independent pharmacy affiliation status. Other characteristics of the final sample are represented in slightly different proportions than exist in the population of Medi-Cal provider pharmacies due to the stratification techniques used in the sample selection process. Due to the use of these stratification protocols, further analysis is indicated to determine whether there is a significant difference in acquisition costs of the various pharmacy specialties. This issue is further addressed in the "Analysis and Findings" section of this chapter.

From the invoices received, the drug purchase date, NDC number, drug name, strength, package size, quantity purchased, and extended price paid were entered into a database. Myers and Stauffer reviewed and edited the database, eliminating data entry errors. Data was input from 372,341 invoice line items (representing purchases of approximately $42 million). Of these, there were 211,456 line items that matched the list of 2,000 drugs. Acquisition cost data for 1,814 of the 2,000 sample drug products is included in the study.

Many chain pharmacies operate a product warehouse that acts as a storage and distribution center for member chain stores and often operates as a profit center. Some of the chains submitted internally generated invoices for their drug purchases. The prices on these internal invoices reflected the warehouse cost of drugs and generally not true arms-length transactions. Although these invoices

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may include legitimate warehousing operational costs, they may also include a profit factor.

There were 215 chain stores in the sample of 491 that submitted internally produced invoices for the vast majority of drug purchases. The drug prices reflected on these invoices created some concerns regarding their validity. These concerns could not always be resolved during conversations with the submitters; therefore, many of the following findings are reported exclusive of the data from these stores' internal invoices.

Analysis and Findings

Invoice drug purchases were separated into the single source and multi-source categories for analysis. These two groups have distinctly different purchase discounts from AWP. Discounts for single source drug products were generally smaller than discounts for multi-source products. Additionally, the range of discounts for single source products was smaller than the range exhibited by multi-source products.

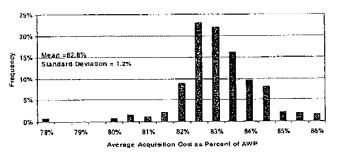The analysis of acquisition cost focused on two areas:

- Distribution of acquisition cost by drug product
- Distribution of acquisition cost by pharmacy and pharmacy type

Single Source Drug Products

The following observations resulted from our analysis of the acquisition cost of single source drugs:

Chart 2.1 Acquisition Cost by Pharmacy
Single Source Products
(Based on External Invoices Only)

- For the 272 pharmacies[3] that provided invoices from external wholesalers, typical acquisition costs for single source drugs ranged from 82% to 84% of the AWP. **The average acquisition cost was 82.8%, with a standard deviation of 1.2%** (see Chart 2.1 and Exhibits 3 and 9).
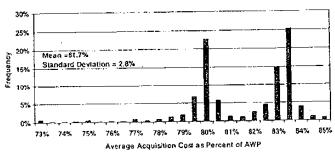
[3] Of the 276 pharmacies with external invoices, there were observations of *single source drugs* from only 272 pharmacies.

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- Including pharmacies that provided invoices from an internal wholesaler, the average acquisition cost for single source drugs was 83.5% of the AWP, with a standard deviation of 1.3%.

- Some of the pharmacies in the sample were institutional providers that dispensed prescriptions to patients in long-term care or other institutional settings. Acquisition costs at these pharmacies for single source drug products averaged 82.1% of the AWP, as compared to 82.9% for pharmacies that dispensed prescriptions in traditional retail settings (see Table 2.4 and Exhibit 9).

- Of the sampled 1,000 single source drugs, 796 drug products were matched to one or more purchases. Of these 796 products, typical acquisition costs for single source drugs ranged from 79% to 84% of the AWP with an average acquisition cost of 81.7% of the AWP (based on observations from external invoices only – see Chart 2.2 and Exhibit 9).

Chart 2.2 Acquisition Cost by Drug Product
Single Source Products
(Based on External Invoices Only)

- The distribution of acquisition costs as a percent of the AWP for single source drug products was bi-modal (see Chart 2.2). Many products had acquisition costs that clustered near the 79% - 81% and 82% - 84% ranges. Drugs of all types fell into each of these ranges and the bi-modal distribution appeared to be a result of manufacturer-specific pricing methodologies (see Exhibit 7).

According to the current Medi-Cal pharmacy reimbursement methodology, drugs from certain labelers are paid on the basis of their Direct Price (DP) rather than the AWP. Myers and Stauffer included an analysis of drug product acquisition cost as compared to the DP as part of the acquisition cost study. Significant observations from this analysis were:

- For the 265 pharmacies[4] that provided invoices from external wholesalers, typical acquisition costs for single source drugs paid with a DP ranged from 93% to 96% of the DP (the 20th and 80th percentiles, respectively). **The**
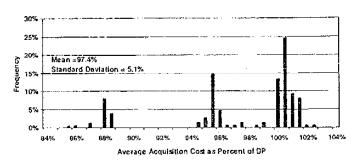
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[4] Of the 276 pharmacies with external invoices, there were observations of *single source drugs paid with a direct price* from only 265 pharmacies.

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average acquisition cost was 94.5%, with a standard deviation of 2.3% (see Exhibit 16).

- Of the sampled 1,000 single source drugs, 151 drug products paid with a DP were matched to one or more purchases. Of these 151 products, typical acquisition costs for single source drugs ranged from 88% to 101% of

Chart 2.3 Acquisition Cost by Drug Product
Single Source Products Paid with a Direct Price
(Based on External Invoices Only)

Mean = 97.4%
Standard Deviation = 5.1%

Average Acquisition Cost as Percent of DP

the AWP with an average acquisition cost of 97.4% of the DP (based on observations from external invoices only – see Chart 2.3 and Exhibit 16).

- There was considerable variation in acquisition cost as a percent of the DP associated with the product lines of various drug labelers (see Exhibit 8). There were five labelers with Direct Prices roughly equal to 100% of pharmacy acquisition cost. Medi-Cal pharmacy payments for single source drugs from these five labelers constitute roughly 50% of the Medi-Cal payments for single source drugs paid with a DP. Three labelers had Direct Prices that averaged 95% of pharmacy acquisition cost (roughly 30% of payments). Finally, one labeler had Direct Prices that were equal to approximately 88% of pharmacy acquisition cost (roughly 20% of payments).

- The variation between drug labeler's direct prices was significantly more pronounced than labeler-specific differences in the relationship between pharmacy acquisition cost and the AWP. Over 90% of labelers' average discount from the AWP fell within the range of 78% to 85% of the AWP (compare Exhibit 7 and 8).

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Multi-Source Drug Products

Although multi-source drug products are an important part of the Medi-Cal drug program, they account for a much smaller portion of program expenditures than single source products. Table 2.3 summarizes findings for multi-source products. A more in-depth treatment of multi-source product acquisition cost is included as an appendix.

Table 2.3 Multi-Source Drug Product Acquisition Cost Findings

	Average Acquisition Cost as a Percent of Given Price Type[A]		
Price Type	Products without an FUL Price	Products with an FUL Price	Exhibit References
AWP	56.6%	12.7%	12, 13
DP	90.4%	N/A	17
FUL	N/A	38.7%	18
MAIC	50.2%	N/A	19

[A] Percentages shown are the averages by drug product and are weighted by Medi-Cal utilization.

Analysis of Pharmacy Characteristics

In addition to analyzing the distribution of the acquisition cost of drugs by pharmacy and individual product, other characteristics were examined to determine statistical significance. These characteristics include:

- Institutional versus Retail Pharmacy Setting
- Chain versus Independent Pharmacy Affiliation
- Urban versus Rural Pharmacy Location
- Provision of Intravenous Prescription Services
- Provision of Compounding Services

For many of these characteristics, limiting the analysis to single source drug products was preferable because of the wide variation in acquisition cost of multi-source products. A wide variation in cost can make apparent differences statistically insignificant. It also is reasonable to limit some analyses to single source products because Medi-Cal expends a high proportion of its drug budget on prescriptions for these products.

In Tables 2.4 through 2.8, findings are expressed in terms of means and standard deviations. Exhibits 9 through 19 provide additional statistical measures including the standard error of the mean, confidence intervals and percentile rankings. Through these statistical measures, recognition is given to the fact that the data available in this analysis represents only a sample of the total population.

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However, characteristics of the data, such as standard deviation and sample size, enable a reasonable prediction of the range in which the true population average lies.

Confidence intervals given in Exhibit 9 were calculated using appropriate statistics from the *t* distribution at the 95% confidence level. These intervals are a range estimate for the population mean, and are based upon the sample mean, standard deviation, and sample size. A 95% confidence interval identifies the range which one would expect the mean from *any* sample to fall 95% of the time. It can be inferred that there is a 95% probability that the population mean lies within the range of the confidence interval.

The following statistics of pharmaceutical acquisition cost, unless stated otherwise, include only pharmacies that submitted external invoices.

1) Institutional Versus Retail Pharmacy Setting

There were 18 institutional pharmacies that dispensed prescriptions primarily to patients in long-term care settings as opposed to retail pharmacies that primarily dispensed prescriptions to ambulatory patients.

An analysis to determine the difference in acquisition cost between the institutional and retail pharmacies is best accomplished through a t-test.

Table 2.4 Institutional Versus Retail Pharmacies

Type of Pharmacy	Number of Observations	Number of Pharmacies	Acq. Cost as % of AWP	Standard Deviation
Institutional	2,804	18	82.1%	1.4%
Retail	40,414	254	82.9%	1.1%

Note: Observations are for Single Source Drug Products Only

The difference in pharmacy average acquisition cost as a percent of the AWP between institutional and retail pharmacies (with institutional pharmacies averaging lower acquisition costs) was statistically significant at the 5% level of significance (for purchases of single source drug products). It is hypothesized that an institutional pharmacy's enhanced ability to direct utilization of certain drug products (by virtue of consulting pharmacists) allows for moderately larger purchase discounts.

Previously it was mentioned that institutional pharmacies were disproportionately represented (via stratification protocols) in the population of pharmacies selected to participate to the acquisition cost survey. Accordingly, many of the findings presented in various exhibits have been segregated based on the institutional or retail status of the responding pharmacies.

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2) Chain Versus Independent Pharmacy Affiliation

The difference in acquisition cost between chain and independent pharmacies was found to be significant for single source drug products. This analysis was limited to chain pharmacies that submitted invoices from external wholesalers. Chain pharmacies had average acquisition costs for single source drugs lower than their independent counterparts.

Table 2.5 Chain Versus Independent Pharmacies (Retail Only)

Type of Pharmacy	Number of Observations	Number of Pharmacies	Mean Acq. Cost as % of AWP	Standard Deviation
Chain	9,789	28	82.1%	0.6%
Independent	30,625	226	83.0%	1.1%

Note: Observations are for Single Source Drug Products Only

As previously noted, several of the chains perform an internal warehousing and wholesaling function and supplied in-house invoices for this study. It is possible that the actual acquisition costs incurred by chain pharmacies, net of warehousing and distribution costs, is less than indicated on an internal invoice. The average acquisition cost for the 243 chain pharmacies (including both internal and external invoices) was 84.1% of the AWP. However, as this average includes observations of non "arms-length transactions," it does not appear to represent reasonable acquisition cost net of internally derived profit factors.

3) Urban Versus Rural Pharmacy Location

Myers and Stauffer used the zip code of each pharmacy to determine if it was located in a Metropolitan Statistical Area as used by the Centers for Medicare and Medi-Cal Services (CMS, formerly HCFA). Only in-state pharmacies were included in this analysis. The pharmacy's location in an urban or rural area was not found to be significant (for single source drug products at the 5% level of significance).

Table 2.6 Urban Versus Rural Location (Retail Only)

Type of Pharmacy	Number of Observations	Number of Pharmacies	Mean Acq. Cost as % of AWP	Standard Deviation
Urban	31,472	217	82.9%	1.1%
Rural	8,942	37	82.6%	1.3%

Note: Observations are for Single Source Drug Products Only

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4) Provision of Intravenous Prescription Services

Myers and Stauffer differentiated pharmacies based on their provision of intravenous prescription dispensing services. A pharmacy's inclusion or exclusion of this service was not found to have statistical significance with regard to the average pharmacy acquisition cost as a percent for the AWP (for single source drug products at the 5% level of significance).

Table 2.7 Provision of Intravenous Prescription Services (Retail Only)

Type of Pharmacy	Number of Observations	Number of Pharmacies	Mean Acq. Cost as % of AWP	Standard Deviation
Provides IV Services	2,152	12	82.9%	1.1%
Does Not Provide IV Services	41,066	260	82.0%	1.8%

Note: Observations are for Single Source Drug Products Only

5) Provision of Compounding Services

Myers and Stauffer differentiated pharmacies based on their provision of compounding dispensing services. A pharmacy's inclusion or exclusion of these services was not found to have statistical significance with regard to the average pharmacy acquisition cost as a percent for the AWP (for single source drug products at the 5% level of significance).

Table 2.8 Provision of Compounding Services

Type of Pharmacy	Number of Observations	Number of Pharmacies	Mean Acq. Cost as % of AWP	Standard Deviation
Provides Compounding Services	2,393	13	82.8%	0.1%
Does not Provide Compounding Services	40,825	259	82.8%	1.2%

Note: Observations are for Single Source Drug Products Only

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Analysis of Drug Characteristics

Attention was also given to classifications of drug products to determine possible effects on acquisition cost. Acquisition cost for single source drugs (as a percent of the AWP) were arrayed by their classification to determine if the drugs' therapeutic use played a role in determining the discount from the AWP.

Table 2.9 Acquisition Cost by Drug Classification

Drug Classification	Number of Observations	Number of Products	Mean Acq. Cost as % of AWP	Standard Deviation
Miscellaneous Antipsychotic Agents	3,452	36	83.4%	2.1%
Proton Pump Inhibitors	5,451	13	83.7%	1.7%
HMG-COA Reductase Inhibitors	8,439	24	82.7%	1.8%
SSRI Antidepressants	7,995	20	83.9%	1.8%
COX-2 Inhibitors	3,450	10	81.7%	2.0%
Miscellaneous Anticonvulsants	5,138	38	83.7%	2.0%
Miscellaneous Hormones (includes Serostim)	1,720	16	82.7%	3.2%
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors	1,263	19	83.6%	1.6%
Calcium Channel Blocking Agents	5,007	33	81.0%	4.7%
Non-Sulfonylureas	3,672	9	84.0%	0.6%
Miscellaneous Anxiolytics, Sedatives	2,423	9	83.0%	1.7%
Antihistamines	5,314	12	82.2%	2.4%
All Other	83,809	594	82.6%	2.9%

Note: Observations are for single source drug products from all pharmacies in sample (internal and external invoices).

Although some of the differences in acquisition cost between drug classification are statistically significant, the breakdown of acquisition costs by classification primarily serves to reinforce the conclusion that discounts for single source drug products are almost universally available and consistent. **We did not find any class of drugs for which discounts from the AWP were not available.**

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Probability Distribution Analysis

The acquisition cost study was performed using a sample of 276 pharmacies (which submitted external invoices) from a total population of about 5,902 Medi-Cal pharmacy providers. Acquisition cost as a percent of the AWP for single source drug products was relatively consistent among providers and drug products. Based on our prior experience, the level of discounts was consistent with our observations from other states. The low variance in acquisition cost allows us to draw conclusions regarding average acquisition cost from the sample and project them to the population of Medi-Cal pharmacy providers.

Earlier comments on the acquisition cost of single source products focused on two significant distributions:

- Acquisition cost by drug product
- Acquisition cost by pharmacy

If the distribution of acquisition cost of pharmacy providers and drug products can be assumed to have a normal distribution, there are certain estimates that can be made about the entire population. The most meaningful estimates include:

- The percent of pharmacies that may be unable to obtain a certain level of discount.
- The percent of drugs that may have an acquisition cost higher than a specified level.

These estimates are summarized in Table 2.10 and refer only to single source drug products.

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Table 2.10 Probability Distribution for Single Source Drugs (Retail Only)[5]

Level of Acquisition Cost (as % of AWP)	Estimated Percent of Pharmacies with a Higher Average Acquisition Cost	Estimated Percent of Single Source Drug Products with a Higher Average Acquisition Cost
90%	0.0%	0.1%
89%	0.0%	0.4%
88%	0.0%	1.1%
87%	0.0%	2.7%
86%	0.3%	5.9%
85%	3.1%	11.6%
84%	15.9%	20.2%

Additionally, based on the low variance exhibited by single source drugs, a relatively small confidence interval exists for the mean acquisition cost. The true mean acquisition cost for the *entire population* is unknown and cannot reasonably be determined since surveying the entire pharmacy population would be cumbersome if not impossible. However, the sample mean and standard deviation allows certain conclusions to be made about the population mean. For the 276 pharmacies in the sample that provided external invoices (retail and institutional), the mean of each store's average acquisition cost as a percent of the AWP was 82.8% with a standard deviation of 1.2%. A 95% confidence interval for the mean ranges from 82.7% to 83.0%. This means that for *any* random sample taken from the population, we would expect the sample mean to fall in the confidence interval range 95% of the time[6].

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[5] Estimates in Table 2.10 were derived from the standard normal distribution and are based on the data from the 276 pharmacies that supplied external invoices. The distribution of acquisition cost in retail pharmacies for single source drug products actually has a negative skew. This means that the assumption of a normal distribution has slightly *overstated* the actual probabilities. Hence, there are likely to be *fewer* pharmacies or drug products with average acquisition costs higher than 84% of the AWP than shown by Table 2.10.

[6] Additional confidence intervals are provided in Exhibits 9 through 19. The Central Limit Theorem of statistics suggests that for sufficiently large numbers of samples, the sample mean will be distributed *approximately* normal. Hence, the assumption of normality in the construction of confidence intervals is appropriate. The construction of the confidence intervals cited here and in the Exhibits was based upon the Student *t* distribution. The *t* distribution is more appropriate for small sample sizes and produces a more conservative (larger) confidence interval than would the use of the normal distribution.

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Appendix A. Acquisition Cost of Multi-Source Drugs

For analysis purposes, multi-source drug products were grouped in two categories: drugs with an FUL price and drugs without an FUL price. The distributions of acquisition cost for these two groups are significantly different.
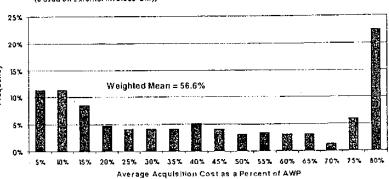
1) Multi-Source Drug Products with No FUL Prices

For some multi-source drug products without federal upper limits, the acquisition cost as a percent of the AWP is similar to those of single source drugs. However, there are a significant number of products purchased with acquisition costs much lower than the 80% to 85% range observed for single source drugs. Our analysis resulted in the following findings (referring to observations from external invoices):

- The average acquisition cost by pharmacy was 64.6% of the AWP (see Exhibit 12).

- Of the 669 products observed, the weighted average acquisition cost was of 56.6% of the AWP (see Chart A.1 and Exhibit 12).

- Approximately one-fourth of these drug products fell in the 80% to 85% acquisition cost range (similar to single source drugs) with the remainder of drugs having acquisition costs as low as 5% of the AWP (see Chart A.1).
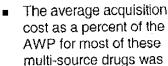
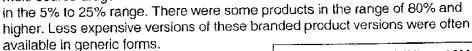- For the 240 pharmacies that provided invoices from external wholesalers, average acquisition costs for multi-source drugs without an FUL and paid with a DP was 93.7% of the DP (see Exhibit 17).

Chart A.1 Acquisition Cost by Drug Product
Multi Source Drug Products without an FUL Price
(Based on External Invoices Only)

Weighted Mean = 56.6%

Average Acquisition Cost as a Percent of AWP

2) Multi-Source Drug Products with FUL Prices

The acquisition costs of multi-source drug products with an FUL price are distributed in a significantly different manner from multi-source products without an FUL. Observations based on analysis of these acquisition costs (from external invoices) follow:
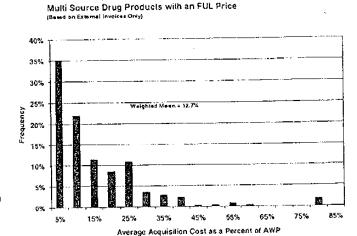
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- The average acquisition cost by pharmacy was 14.1% of the AWP (see Exhibit 13).

- There were 233 drug products matched with invoice purchase line items. Acquisition cost as a percent of the AWP for these products had a weighted average acquisition cost of 12.7% of the AWP (see Chart A.2 and Exhibit 13).

- The average acquisition cost as a percent of the AWP for most of these multi-source drugs was

Chart A.2 Acquisition Cost by Drug Product Multi Source Drug Products with an FUL Price
(Based on External Invoices Only)

in the 5% to 25% range. There were some products in the range of 80% and higher. Less expensive versions of these branded product versions were often available in generic forms.

The acquisition cost of these multi-source products was also analyzed as a percentage of their FUL price. The following findings resulted from that analysis:

- Acquisition cost by pharmacy as a percent of the FUL price was an average of 44.2% of the FUL price (see Exhibit 18).

- The average acquisition cost as a percent of FUL exceeded 100% for some pharmacies. These averages were typically highly skewed by the purchase of a brand name product for which a generic alternative is available.

- For individual drug products, acquisition cost as a percent of the FUL was a weighted average of 38.7% of the FUL price (see Exhibit 18).

> **Effectiveness of FUL and MAIC Prices**
>
> The Medi-Cal pharmacy program currently reimburses the lesser of the Estimated Acquisition Cost (EAC – currently AWP minus 5% or Direct Price), FUL or MAIC price.
>
> For calendar year 2000, approximately $182 million in savings was obtained by reimbursing the FUL price instead of the EAC price.
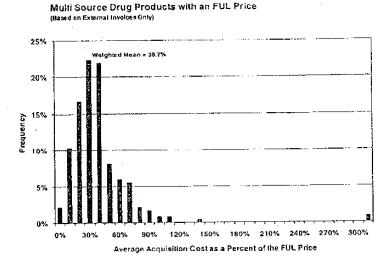>
> MAIC prices also produce savings, yet to a less significant degree than savings realized by FUL prices. MAIC prices existed for approximately 600 drug products that were reimbursed by Medi-Cal. Annual savings realized by using MAIC prices are estimated to be approximately $6 million.

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- The acquisition cost as a percent of the FUL price for most of these multi-source products was in the 5% to 80% range. A small number of products fell in the range of 100% or higher (see Chart A.3). Less expensive generic versions are typically available for these brand name products. In theory, the branded version of these products should only be dispensed to Medi-Cal patients on occasions when a physician has indicated that the brand name product is "medically necessary." **In those instances, the product would be reimbursed using the EAC rate (e.g. AWP minus 5%), not the FUL.**

Chart A.3 Acquisition Cost by Drug Product
Multi Source Drug Products with an FUL Price
(Based on External Invoices Only)

3) Multi-Source Drugs with a California Maximum Allowable Ingredient Cost (MAIC) Price

The analysis of multi-source drugs included examining the acquisition cost of drugs as a percent of the MAIC price. The following observations were made:

- For the 216 pharmacies with one or more observations, average acquisition cost as a percent of the MAIC price was 39.1% (see Exhibit 19).

- For individual drug products, acquisition cost as a percent of the MAIC was a weighted average of 50.2% of the MAIC price (see Chart A.4 and Exhibit 19).

- The acquisition cost as a percent of the MAIC price for most of these multi-source products was in the 5% to 80% range. A small number of products fell in the range of 100% or higher (see Chart A.4). Less expensive generic versions are available for these branded versions of products. As with drugs with an FUL, the branded version of these products should only be dispensed to Medi-Cal patients on occasions when a physician has indicated that the brand name product is "medically necessary." **In those instances, the product would be reimbursed using the EAC rate (e.g. AWP minus 5%), not the MAIC.**

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